UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

SHERRY ANN WALKER
ADMINISTRATRIX OF THE ESTATE OF ARNOLD LEROY WALKER, JR.
And SHERRY WALKER, individually;

Plaintiff,

v.

MEDTRONIC, INC., a Minnesota corporation;

Defendant.

Case No. 2:07-cv-00317
Hon. David A. Faber

DEFENDANT MEDTRONIC, INC.'S OBJECTIONS TO PLAINTIFF'S SECOND 30(B)(6) NOTICE OF DEPOSITION OF DEFENDANT MEDTRONIC, INC.

TO: PLAINTIFF SHERRY WALKER, BY AND THROUGH HER ATTORNEYS CHRISTOPHER L. BRINKLEY, THE MASTERS LAW FIRM, LC, 181 SUMMERS STREET, CHARLESTON, WV 25301

Defendant Medtronic, Inc. ("Medtronic") hereby objects to Plaintiff's Second 30(b)(6) Notice of Deposition of Defendant Medtronic, Inc.[1] ("Second Notice") in this action, on the following grounds:

[1] Medtronic has produced voluminous documents to Plaintiff regarding the Model 8627-18 SynchroMed EL infusion pump at issue in this case. For example, Medtronic's entire FDA premarket approval ("PMA") file, comprised of 65,811 pages, was made available for review by Plaintiff's counsel in Minneapolis on two separate occasions: March 9-11, 2009 and April 20-22, 2009. Following this review, Plaintiff's counsel requested that Medtronic produce 17,380 pages from the PMA file. Then, following discussions between counsel concerning a draft, but never served, Rule 30(b)(6) Notice, comprising many of the same issues noted in the Second Notice, agreement was reached between the parties that Medtronic would voluntarily produce two 30(b)(6) witnesses to discuss three distinct areas arguably relevant to the limited issue remaining in this case. Those depositions occurred on June 25 and 26, 2009. One of the witnesses produced was a senior engineer who had been with Medtronic for 34 years (until recently retiring on May 29, 2009) and is among the most knowledgeable engineers within Medtronic in terms of infusion pump design and function.

GENERAL OBJECTIONS

1. Pursuant to the Court's September 9, 2008 Memorandum Opinion and Order, Plaintiff is only entitled to discovery solely on the specific issue of "whether the infusion pump complied with the terms of its premarket approval." *See* 9/9/2008 Memorandum Opinion and Order ("Court's Order") at 7. Medtronic therefore objects to the Second Notice on the grounds that it is seeking testimony on issues that are far outside the scope of discovery left open by this Court's Order. For that reason, the scope of the discovery sought by the Second Notice is unnecessary, unreasonable, and unduly burdensome, and seeks information which is irrelevant or immaterial to the limited issue remaining in this action, to wit: Did Arnold Walker's Model 8627-18 SynchroMed EL Infusion pump comply with the design, manufacturing and labeling requirements approved by the Federal Food & Drug Administration ("FDA") in connection with Medtronic's premarket approval ("PMA") application?

2. Medtronic objects to the Second Notice on the grounds that Plaintiff's claims are preempted by federal law, specifically 21 U.S.C. § 360k(a). *See also Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008). Because preemption is a question of law and depends only upon the evidence indicating that the specific device in question was, and remained, approved by the FDA following its review of Medtronic's PMA application, it is unnecessary, unduly burdensome and oppressive for Plaintiff to depose Medtronic representatives on the categories sought by the Second Notice. Indeed, the FDA's approval of the device is already demonstrated in the voluminous documents that Medtronic has produced to Plaintiff, including the PMA for the device at issue. That fact is not contested by Plaintiff. The only remaining question is whether Mr. Walker's

specific device complied with the FDA's design, manufacturing and labeling requirements.

3. Finally, Medtronic objects to the Second Notice to the extent that it is not limited in scope in terms of either the categories of information being sought or in terms of any reasonable period of time.[2]

With respect to Plaintiff's Category Nos. 1-12, and subject to the general objections set forth, above, Medtronic responds as set forth below:

RESPONSES

1. The PMA process for the Synchromed and Synchromed EL pump systems (the pumps, catheters, programmers, etc.), including the PMA filings and supplemental filings (particularly, but not limited to, the original PMA and Supplements 7, 42, 52, and 55), the supporting testing and other documentation, and any associated correspondence to or from the FDA;

Medtronic incorporates by reference its General Objections. Medtronic further objects to this specific Category on the grounds that it is literally indecipherable in terms of who or what witnesses could possibly respond to this unbounded request.[3] Indeed, it literally would be impossible to produce a witness to address all of the categories conceivably encompassed by the "PMA process" and all of its voluminous filings. Moreover, the

[2] Medtronic also objects to the Second Notice to the extent it calls for the disclosure of information or communications protected by the attorney-client privilege or any other applicable privilege, rule of law, or statute, on the grounds that such matters are exempt from discovery. Medtronic also objects to the Second Notice to the extent it calls for the disclosure of information protected by the work product doctrine, including the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of Medtronic concerning the above-captioned litigation, on the grounds that such information is exempt from discovery; and further objects to the Second Notice to the extent it calls for the disclosure of any information or materials that constitute or include materials protected under the work product doctrine and/or materials prepared in anticipation of litigation.

[3] The "PMA process . . . including the PMA filings" covers almost three decades, from the 1980s to the present. As described in Footnote 1, above, the PMA file produced to Plaintiff's counsel for review included 65,811 pages.

65,000-plus pages submitted to Plaintiff's counsel for his review speak for themselves in terms of explaining the FDA's rigorous PMA process and outline in detail the terms of both Medtronic's submission for, and the FDA's approval of, the device at issue. Thus, the information sought by Category No. 1 has already been produced to Plaintiff through document discovery. In light of the limited issue remaining before this Court, as outlined in the Court's Order, it is therefore unnecessary, unduly burdensome, duplicative, cumulative, and unreasonable to also depose a Medtronic representative regarding the "PMA process."

2. Reports, complaints, failure rates, and the causes thereof related to incidents of over infusion by Synchromed and Synchromed EL pump systems (the pumps, catheters, programmers, etc.); [note that this area of inquiry is intended to reports to Medtronic, Medical Device Reports, Adverse Event Reports, Product Comment Reports, MedWatch reports, etc.];

Medtronic incorporates by reference its General Objections and the objections referenced in Category 1, above. In addition, Medtronic further objects to this Category on the grounds that it seeks to require Medtronic to disclose and/or discuss confidential information that implicates the privacy concerns of third parties. Medtronic therefore objects to this Category because Medtronic is prohibited from disclosing patient and/or physician/hospital information under federal statutory and regulatory law, including 21 U.S.C. § 360i(b)(3) and 21 C.F.R. 20.63(f). *See In re Medtronic*, 184 F.3d 807 (8th Cir. 1999); *see also* Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

3. The manner of surgical implantation, programming, filling, and refilling of the Synchromed and Synchromed EL pump systems (the pumps, catheters, programmers, etc.); any instruction or training provided to treating physicians; any warnings or pre-cautions provided; any aids or "tools" offered or provided by the Defendant used to facilitate implantation, programming, filling, and refilling of the Synchromed and Synchromed EL pump systems; and the observation or participation of any of Defendant's representatives in the implantation, programming, filling, and refilling of the Synchromed and Synchromed EL pump systems; [note that

> this area of inquiry is intended to include both general practice and Mr. Walker's pump specifically];

Medtronic incorporates its General Objections and the additional objections referenced in connection with Category 1, above. Medtronic objects to this Category because it already has produced to Plaintiff the entire PMA file which as well as the device's FDA-approved labeling, warnings, and instructions, all of which demonstrate Medtronic's compliance with the labeling requirements imposed by the FDA in connection with Mr. Walker's specific device. These materials discuss the FDA-approved requirements for the "implantation, programming, filling, and refilling" of Mr. Walker's infusion pump. It is therefore unnecessary, unduly burdensome, duplicative, cumulative, and unreasonable to also depose a Medtronic representative regarding the information sought in Category No. 3, contained within the FDA approved labeling, which discusses all of these issues and which documents speak for themselves. Finally, and perhaps most importantly, Medtronic objects to this Category on the grounds that the discovery sought is obtainable—and, indeed, is already being scheduled—from other sources with first-hand knowledge of all of these issues as they pertain to Mr. Walker's pump. In particular the parties have scheduled the deposition of the physician who implanted Mr. Walker's pump, Dr. J. K. Lilly. Dr. Lilly's deposition is scheduled to take place on July 27, 2009. The parties can, and no doubt will, depose several other treating physicians who filled and/or refilled the pump from the time of its implantation until the date of Mr. Walker's death on June 9, 2005, to obtain all of the information sought by Category 3.[4]

[4] Subject to and without waiving its objections, if it is established that any currently employed Medtronic representative participated in the implantation, programming, filling, or refilling of Mr. Walker's Model 8627-18 infusion pump, Medtronic will produce that witness to testify regarding his or her specific observations concerning Mr. Walker's device.

4. Contraindications and potential complications (and the causes thereof) associated with use of Synchromed and Synchromed EL pump systems (the pumps, catheters, programmers, etc.); [note that this area of inquiry is intended to include both general practice and Mr. Walker's pump specifically];

Medtronic incorporates its General Objections and the additional objections referenced in connection with Categories 1 through 3, above. As noted previously, Medtronic has produced to Plaintiff the FDA-approved labeling for Mr. Walker's device which contains information regarding the device's "contraindications and potential complications" and the documents speak for themselves. It is therefore unnecessary, unduly burdensome, duplicative, cumulative, and unreasonable to depose a Medtronic representative regarding Category No. 4.

5. Anticipated performance and results associated with a successful implantation, programming, filling, refilling, and operation of Synchromed and Synchromed EL pump systems (the pumps, catheters, programmers, etc.); [note that this area of inquiry is intended to include both general practice and Mr. Walker's pump specifically];

Medtronic incorporates its General Objections and the additional objections referenced in connection with Categories 1 through 4, above. Medtronic further objects to this category because the phrase "anticipated . . . results associated with a successful implantation" is vague and ambiguous. Notwithstanding, and without waiving this objection, Medtronic already has produced to Plaintiff the FDA-approved labeling for Mr. Walker's device which contains information regarding its expected "performance, . . . programming, filling, refilling, and operation" and the documents speak for themselves. In addition, one of Medtronic's 30(b)(6) designated witnesses, George Mohar, generally addressed "anticipated performance results" during his recent deposition. It therefore is unnecessary, unduly burdensome, duplicative, cumulative, oppressive and unreasonable to request a Medtronic representative to testify regarding Category No. 5.

6. Implantation, programming, filling, and refilling of the pump implanted into Mr. Walker;

Medtronic incorporates its General Objections and the additional objections referenced in connection with Categories 1 through 5, above. In particular, see Medtronic's specific objection to Category 3, above, concerning the pending discovery from the health care providers who possess first-hand knowledge of these issues as they relate specifically to Mr. Walker and to his infusion pump.

7. Any engineering failure modes and effects analyses, hazard analyses, risk analyses associated with the design and operation of the Synchromed and Synchromed EL pump systems (the pumps, catheters, programmers, etc.);

Medtronic incorporates its General Objections and the additional objections referenced in connection with Categories 1 through 6, above. Medtronic further objects to this Category on the grounds that the phrase "engineering failure modes and effects analyses, hazard analyses [and] risk analyses associated with the design and operation" is vague and ambiguous. The hazards and risks associated with the implantation and use of the pump are fully set forth in the FDA-approved labeling, all of which has been produced to Plaintiff as part of the PMA file.

8. The operating software for the pump and the software for programming the pump which was implanted into Mr. Walker, including the evolution of and changes to those pieces of software from the time the initial PMA was approved to present;

Medtronic incorporates its General Objections and the additional objections referenced in connection with Categories 1 through 7, above. Moreover, any evolution of the software over time is irrelevant and unrelated to the issue of whether Mr. Walker's specific device met the FDA's PMA requirements.

9. All potential causes for overinfusion by Synchromed and Synchromed EL pump systems (the pumps, catheters, programmers, etc.);

Medtronic incorporates its General Objections and the additional objections referenced in connection with Categories 1 through 8, above. Medtronic further objects to this Category because it has already produced to Plaintiff the entire PMA file, as well as the device's FDA-approved labeling, warnings, and instructions, all of which discuss, among other risks, potential causes for overdose or "overinfusion." *See, e.g.*, pages 3 – 7 of Medtronic's SynchroMed® EL Programmable Pumps Technical Manual (dated 2002) under the headings "CONTRAINDICATIONS" and "WARNINGS." The information sought by Category No. 9 has therefore already been produced to Plaintiff through document discovery and the documents speak for themselves.

10. The pump settings, performance characteristics, their ranges, and their tolerances (including, but not limited to, infusion rates, infusion modalities, allowable medications and concentrations thereof, etc.) for the Synchromed and Synchromed EL pump systems (the pumps, catheters, programmers, etc.); [note that this area of inquiry is intended to include both general practice and Mr. Walker's pump specifically];

Medtronic incorporates its General Objections and the additional objections referenced in connection with Categories 1 through 9, above. The information sought by Category No. 10 has therefore already been produced to Plaintiff through document discovery and the documents speak for themselves. In addition, Medtronic has already produced a witness (George Mohar) who was knowledgeable on several of these subjects and he has already been deposed. *See* footnote 1, above.

11. The patents applicable to the Synchromed and Synchromed EL pump systems (the pumps, catheters, programmers, etc.); and

Medtronic incorporates its General Objections and the additional objections referenced in connection with Categories 1 through 10, above. Like all of Plaintiff's categories, above,

there is no conceivable reason to produce the patents for the device, much less to produce a witness or witnesses to discuss them.

12. Defendant's discovery responses and the documents produced; Defendant Medtronic, Inc. shall designate and produce one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and shall set forth, for each person designated, the matters on which he or she will testify. The person(s) so designated shall testify as to matters known or reasonably available to the organization.

Medtronic incorporates its General Objections and the additional objections referenced in connection with Categories 1 through 11, above. Medtronic further objects to this Category because there simply is no conceivable purpose for Plaintiff to even make this request. Finally, Medtronic reasserts its objection to this Category because it calls for the disclosure of attorney-client privileged information and/or work product privileged information. This request appears designed for no purpose other than to harass Medtronic.

Dated: July 6, 2009

SPILMAN THOMAS & BATTLE, PLLC

By: /s/ Paula L. Durst _____

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CERTIFICATE OF SERVICE

I hereby certify that on July 6, 2009, I electronically filed the foregoing **"Defendant Medtronic, Inc.'s Objections to Plaintiff's Second 30(B)(6) Notice of Deposition of Defendant Medtronic, Inc."** with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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